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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,520	02/09/2007	Yifei Huang	SPRU-04	8970

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EXAMINER	
BEHRINGER, LUTHER G	

ART UNIT	PAPER NUMBER
4148	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,520	HUANG ET AL.	
	Examiner	Art Unit	
	LUTHER G. BEHRINGER	4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/07/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to application no. 10/567520 filed on 02/09/2007.

Specification

2. The disclosure is objected to because of the following informalities: On page 3, and sporadically throughout the application, the spelling utilized for pressurisable, pressurisation, pressurise and other variants of the word pressurize is inconsistent with US convention and practice.

3. On page 3, line 17, the language of the following phrase seems incorrect: "The left patch device 1a is positioned engaged with".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim(s) 1 – 5 are rejected under 35 U.S.C. 102(b) as being anticipated by **Woodard et al. (WO 98/55165, herein Woodard)**.

Regarding **claim 1,** Woodard discloses an implantable direct cardiac compression device comprising: a body having a flexible frontal cardiac compression

wall, **95**, and a rear wall, **94**, together defining a pressurizable chamber, said cardiac compression wall being adapted to be affixed to the wall of a ventricle of a heart and to compress the ventricle upon pressurization of said chamber, said rear wall being stiffer than said cardiac compression wall, said body having two opposing lateral sides; and two flexible flaps, **107**, one of said flaps extending from one of said lateral sides of said body and the other of said flaps extending from the other of said lateral sides of said body, said flaps being adapted to be affixed, *sutured,* to the ventricle wall (Page 40, Line 14 – Page 41, Line 19 & Figure 12 & Figure 14).

Regarding **claim 2,** Woodard discloses wherein said cardiac compression wall and said flaps each have a surface layer formed of a biointegratable material for affixing to the ventricle wall by biointegrating with the ventricle wall (Page 40, Lines 20 – 21).

Regarding **claim 3,** Woodard discloses wherein each of said flaps is able to be trimmed with the use of scissors or the like (Page 41, Lines 6 – 9).

Regarding **claim 4,** Woodard discloses wherein said cardiac compression wall is adapted to be affixed to the left ventricle of a heart (Abstract).

Regarding **claim 5,** Woodard discloses wherein said flaps each comprise said flap surface layer and a reinforcing layer secured to said flap surface layer for suturing to the pericardium encasing the heart (Page 41, Lines 15 – 19).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim(s) 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Woodard et al. (WO 98/55165, herein Woodard)** in view of **Rubin (US 5,910,124)**.

Regarding **claim 6,** Woodard discloses a method of treating a failing heart comprising the steps of: providing a left implantable direct cardiac compression (DCC) device having a body comprising a flexible frontal cardiac compression wall, **95**, and a rear wall, **94**, together defining a pressurizable chamber, **A, B, C, D, or E**, said left DCC device rear wall being stiffer than said left DCC device cardiac compression wall, said left DCC device further having two flexible flaps, **107**, one said flap extending from one lateral side of said left DCC device body and the other of said flaps extending from an opposing lateral side of said left DCC device body; introducing a right direct cardiac compression (DCC) device through said incision into the pericardial space of the patient, said right DCC device having a body comprising a flexible frontal cardiac compression wall, **95**, and a rear wall, **94**, together defining a pressurizable chamber, **A, B, C, D, or E**, said right DCC device rear wall being stiffer than said right DCC device

compression wall; securing said right DCC device cardiac compression wall to the right ventricle of the heart; securing said left DCC device cardiac compression wall and flaps, **107**, to the left ventricle of the heart; periodically pressurizing said chamber of each of said left and right DCC devices to assist contraction of the left and right ventricles during systole (Page 40, Line 14 – Page 41, Line 19 & Figure 12 & Figure 14).

Woodard fails to disclose creating an incision through the chest of a patient to be treated, said incision extending through the pericardium of the patient; introducing a left implantable direct cardiac compression (DCC) device through said incision into the pericardial space of the patient.

However, Rubin teaches a method that includes creating an incision through the chest of a patient to be treated, said incision extending through the pericardium of the patient; introducing a left implantable direct cardiac compression (DCC) device through said incision into the pericardial space of the patient (Col. 3, Lines 15 – 49).

9. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of improved methods of implantation as taught by Rubin to achieve effective implantation of the cardiac assist device. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try the improved implantation method as taught by Rubin, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

10. Regarding **claim 8,** Woodard discloses wherein said right DCC device cardiac compression wall and said left DCC device cardiac compression wall and flaps are

secured to the right and left ventricles respectively by biointegrating with the right and left ventricles respectively (Page 41, Lines 5 – 9).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Woodard et al. (WO 98/55165, herein Woodard)** in view of **Rubin (US 5,910,124)** as applied to **claim 6** and further in view of **Ramos Martinez (US 5,133,744, herein Ramos)**.

Regarding **claim 7,** Woodard in view of Rubin disclose all the limitations as stated above, but fails to disclose the step of securing each of said flaps to the pericardium on opposing sides of said incision.

However, Ramos teaches the method of assisting heart function further comprising the step of securing each of said flaps to the pericardium on opposing sides of said incision (Col. 3, Lines 61 – 66).

12. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of securing the DCC to achieve cardiac compression. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try securing method as taught by Ramos, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

13. Claim(s) 9 – 10 and 12 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Woodard et al. (WO 98/55165, herein Woodard)** in view of **Grooters (US 5,131,905)**.

Regarding **claim 9,** Woodard discloses an implantable direct cardiac compression system comprising: a left implantable direct cardiac compression (DCC) device having a body comprising a flexible frontal cardiac compression wall, **95**, and a

rear wall, **94**, together defining a pressurizable chamber, **A, B, C, D, or E**, said left DCC device cardiac compression wall being adapted to be affixed to the left ventricle of a heart and to compress the left ventricle upon pressurization of said left DCC device chamber, said left DCC device rear wall being stiffer said left DCC device cardiac compression wall; a right implant, able direct cardiac compression (DCC) device having a body comprising a flexible frontal cardiac compression wall and a rear wall together defining a pressurizable chamber, said right DCC device cardiac compression wall being adapted to be affixed to the right ventricle of the heart and to compress the right ventricle upon pressurization of said right DCC device chamber, said right DCC device rear wall being stiffer than said right DCC device cardiac compression wall(Page 40, Line 14 – Page 41, Line 19 & Figure 12 & Figure 14).

Woodard fails to disclose wherein said body of one of said DCC devices is provided with at least one strap extending from opposing lateral sides thereof and adapted to extend around the heart and said body of the other of said DCC devices in use.

However, Grooters teaches an implantable DCC system wherein said body of one of said DCC devices is provided with at least one strap extending from opposing lateral sides thereof and adapted to extend around the heart and said body of the other of said DCC devices in use (Col. 3, Lines 29 – 33).

14. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of securing the DCC to achieve cardiac compression. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the

invention to try securing technique as taught by Grooters, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 10,** Woodard discloses wherein said right DCC device comprises said one DCC device and said left DCC device comprises said other DCC device.

Regarding **claim 12,** Woodard discloses wherein said straps are formed of a bioabsorbable material (Page 40, Lines 20 – 21).

Regarding **claim 13,** Woodard in view of Grooters discloses all of the limitations of claim 10 but fails to disclose wherein said right DCC device is provided with two said straps each extending from each lateral side of said right DCC device body.

However, Grooters teaches an implantable DCC system wherein said right DCC device is provided with two said straps each extending from each lateral side of said right DCC device body.

15. It would have been obvious to a person having ordinary skill in the art at the time of the invention to use multiple straps to secure the DCC, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

Regarding **claim 14,** Woodard discloses wherein said cardiac compression wall of each said DCC device has a surface layer formed of a biointegratable material for affixing to the respective ventricle wall by biointegrating with the respective ventricle wall (Page 40, Lines 20 – 21).

Regarding **claim 15,** Woodard discloses wherein said left DCC device is provided with two flexible flaps, **107**, one of said flaps extending from a lateral side of said body and the other said flaps extending from an opposing lateral side of said body, said flaps adapted to be fixed to the left ventricle wall (Figure 12).

Regarding **claim 16,** Woodard discloses wherein each of said flaps is able to be trimmed with the use of scissors or the like (Page 41, Lines 6 – 9).

Regarding **claim 17,** Woodard discloses wherein said flaps each have a surface layer formed of a biointegratable material for affixing to the left ventricle wall by biointegrating with the left ventricle wall (Page 40, Lines 20 – 21).

16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Woodard et al. (WO 98/55165, herein Woodard)** in view of **Grooters (US 5,131,905)** as applied to **claim 10** and further in view of **Gellman et al. (US 6,042,534, herein Gellman)**.

Regarding **claim 11,** Woodard in view of Grooters discloses all of the limitations of claim 10 but fails to disclose wherein said left DCC device is provided with one or more eyelets adapted to receive said straps.

However, Gellman teaches an implantable device provided with one or more eyelets adapted to receive said straps, *fasteners* (Paragraph [0047]).

17. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of securing the DCC utilizing eyelets to achieve cardiac compression thereby increasing stability during immediate post operation, prior to biointegration of the DCC. Thus, it would have been obvious to a person having

ordinary skill in the art at the time of the invention to try securing method as taught by Gellman, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

18. Claim(s) 18 and 20 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Woodard et al. (WO 98/55165, herein Woodard)** in view of **Rubin (US 5,910,124)** and further in view of **Grooters (US 5,131,905)**.

Regarding **claim 18,** Woodard discloses a method of treating a failing heart comprising the steps of: introducing a left implantable direct cardiac compression (DCC) device; said left DCC device having a body comprising a flexible frontal cardiac compression wall, **95**, and a rear wall, **94**, together defining a pressurizable chamber, **A, B, C, D, or E**, said left DCC device rear wall being stiffer than said left DCC device cardiac compression wall; introducing a right direct cardiac compression (DCC) device through said incision into the pericardial space of the patient, said right DCC having a body comprising a flexible frontal cardiac compression wall, **95**, and a rear wall, **94**, together defining a pressurizable chamber, **A, B, C, D, or E**, said right DCC device rear wall being stiffer than said right DCC device cardiac compression wall, positioning said right DCC device cardiac compression wall against the right ventricle of the heart; positioning said left DCC device cardiac compression wall against the left ventricle of the heart, and periodically pressurizing said chamber of each of said left and right DCC devices to assist contraction of the left and right ventricles during systole (Woodard: Page 40, Line 14 – Page 41, Line 19 & Figure 12 & Figure 14).

Woodard fails to disclose creating an incision through the chest of a patient to be treated, said incision extending through the pericardium of the patient; introducing a left implantable direct cardiac compression (DCC) device through said incision into the pericardial space of the patient or said right DCC device being provided with at least one strap extending from opposing lateral sides of said right DCC device body; extending said strap(s) around the heart and the left DCC device body; fastening said strap(s) to secure said left and right DCC devices to the left and right ventricles respectively.

However, Rubin teaches a method that includes creating an incision through the chest of a patient to be treated, said incision extending through the pericardium of the patient; introducing a left implantable direct cardiac compression (DCC) device through said incision into the pericardial space of the patient (Col. 3, Lines 15 – 49).

19. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of improved methods of implantation as taught by Rubin to achieve effective implantation of the cardiac assist device. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try the improved implantation method as taught by Rubin, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Woodard in view of Rubin fails to disclose said right DCC device being provided with at least one strap extending from opposing lateral sides of said right DCC device body; extending said strap(s) around the heart and the left DCC device body; fastening

said strap(s) to secure said left and right DCC devices to the left and right ventricles respectively.

However, Grooters teaches said right DCC device being provided with at least one strap extending from opposing lateral sides of said right DCC device body; extending said strap(s) around the heart and the left DCC device body; fastening said strap(s) to secure said left and right DCC devices to the left and right ventricles respectively (Col. 3, Lines 29 – 33).

20. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of securing the DCC utilizing straps to achieve cardiac compression. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try securing method as taught by Grooters, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 20,** Woodard discloses wherein said left and right DCC devices are further secured to the left and right ventricles by biointegration of said cardiac compression walls with the ventricles (Woodard: Page 41, Lines 15 – 19).

Regarding **claim 21,** Woodard discloses wherein said left DCC device is provided with two flexible flaps, **107**, one said flap extending from a lateral side of said left DCC device body, the other said flap extending from an opposing lateral side of said left DCC body, said method further comprising the step of securing said flaps to the left ventricle (Woodard: Page 41, Lines 15 – 19 & Figure 12).

Regarding **claim 22,** Woodard discloses wherein said flaps are trimmed prior to being introduced (Woodard: Page 41, Lines 6 – 9).

21. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Woodard et al. (WO 98/55165, herein Woodard)** in view of **Rubin (US 5,910,124),** further in view of **Grooters (US 5,131,905)** as applied to **claim 18** above, and further in view of **Gellman et al. (US 6,042,534, herein Gellman)**.

Regarding **claim 19,** Woodard in view of Grooters and further in view of Grooters fails to disclose wherein said strap(s) is/are threaded through at least one eyelet provided on the left DCC device.

However, Gellman teaches wherein said strap(s), *fasteners,* is/are threaded through at least one eyelet provided on the left DCC device (Paragraph [0047]).

22. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of securing the DCC utilizing straps threaded through eyelets to achieve stabilized cardiac compression. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try securing method as taught by Gellman, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Anstadt; Mark P. et al., (US 2006/0142634) Hunyor; Stephen**

Nicholas et al., (US 6,918,870) Snyders; Robert V., (US 5,169,381) Kazi; Arif et al., (US 6,206,820), Li (US 2005/0240075).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Luther Behringer
January 23, 2008

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